

## REMARKS

Claims 1-2, 4-18, 20-23, 25, 27-37, 39, and 41 are pending and stand rejected. Applicants respectfully request reconsideration of the present application in view of the above amendments and following remarks.

### *Amendments to the Claims*

Applicants amend independent claims 1, 21, and 25 to recite the features of claims 19, 38 and 40, respectively. No new matter is added.

### *Rejections Pursuant to 35 U.S.C. §102*

#### Malaviya '797

The Examiner rejects claims 1, 2, 4-8, and 10-18 pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Publication No. 2003/0036797 of Malaviya et al. ("Malaviya '797"). Applicants respectfully disagree.

Claim 1 recites that the cell growth conduit flap contacts a tibial surface, extends to the synovium, and communicates biological materials to a tissue defect in the meniscus. Claim 1 also recites that the density of the cell growth conduit flap is in the range of about 150 mg/cc to 350 mg/cc. Applicants submit that claim 1 distinguishes over Malaviya '797 and represents allowable subject matter.

The Examiner argues that "the device of Malaviya ['797] is capable of contacting the tibial surface and extending to the synovium." This is incorrect. According to the teachings of Malaviya '797, the covers 232, 234, which the Examiner argues form the claimed cell growth conduit flap, cannot extend to the synovium. Malaviya '797 teaches that the "adjacent radially outer portion of the original meniscus" is retained and contacts the device. The retained radially outer portion of the original meniscus thus prevents the device from being positioned in a manner that would allow the covers 232, 234 to extend to the synovium. Moreover, even if the device could be positioned such that the covers 232, 234 extended to the synovium, in such a position the device would no longer "conform to the space into which it is inserted such that the surrounding tissue of the remaining meniscus is in contact with the device," as taught by Malaviya '797. See Malaviya '797 at Par. 0018. Therefore, according to the teachings of Malaviya '797, the cell growth conduit flap would not be capable of extending to the synovium.

Nevertheless, as amended, claim 1 also recites that the density of the cell growth conduit flap is in the range of about 150 mg/cc to 350 mg/cc. Malaviya '797 fails to teach or even suggest a cell growth conduit flap with a density in the range of about 150 mg/cc to 350 mg/cc. The Examiner argues that Malaviya '797 discloses that "the covers may have a density in the range of 61-933 mg/cc." Office Action dated June 9, 2009 at page 5, last paragraph. This is entirely incorrect and is a misrepresentation of the disclosure of Malaviya '797. Malaviya '797 actually discloses that "a toughened SIS laminate formed from twenty (20) layers of SIS material compressed in a vacuum bed at a temperature of 30° C. for 1 hour was determined to have a density of about 0.933+/-0.061 g/cm<sup>3</sup>." Malaviya '797 at paragraph 0142. Thus, Malaviya '797 discloses an SIS laminate that has a density of 933 mg/cm<sup>3</sup> plus or minus 61 mg/cm<sup>3</sup>. In other words, Malaviya '797 discloses a density range from 872 mg/cm<sup>3</sup> to 994 mg/cm<sup>3</sup>. The density range disclosed by Malaviya '797 is therefore more than 2.5 times higher than the claimed density range. There is therefore no teaching or suggestion in Malaviya '797 of a cell growth conduit flap of the density range required by claim 1.

Accordingly, independent claim 1 distinguishes over Malaviya '797 and represents allowable subject matter. Claims 2, 4-8, and 10-18 likewise distinguish over Malaviya '797 by virtue of their dependence on claim 1.

***Rejections Pursuant to 35 U.S.C. §103***

**Malaviya '797**

The Examiner rejects claims 9, 19, and 30-33 pursuant to 35 U.S.C. §103(a) as being unpatentable over Malaviya '797. Applicants respectfully disagree with the Examiner's rejection.

At the outset, Applicants note that claim 9 depends from claim 1 and therefore distinguishes over Malaviya '797 for all the reasons discussed above with respect to claim 1. In brief, Malaviya '797 neither teaches nor suggests a cell growth conduit flap that extends to the synovium or with the claimed density.

The features of claim 19 are now recited by claim 1, as amended. In particular, claim 1 recites that the density of the cell growth conduit flap is in the range of about 150 mg/cc to 350 mg/cc. As discussed above, Malaviya '797 fails to teach or suggest the claimed density range. In fact, Malaviya '797 discloses an SIS laminate that has a density range from 872 mg/cm<sup>3</sup> to 994 mg/cm<sup>3</sup>. Thus, contrary to the Examiner's arguments, the density range disclosed by Malaviya '797 does not include the claimed range. In fact, the density range disclosed by Malaviya '797 is

more than 2.5 times *higher* than the claimed density range. Malaviya therefore fails to teach or even suggest the density range required by claim 1.

Claims 30-33 depend from independent claim 21. Claim 21 distinguishes over Malaviya '797 for the reasons discussed in more detail below. In brief, Malaviya '797 fails to teach or suggest the cell growth conduit flap density range recited by claim 21 or positioning a cell growth conduit flap in contact with the synovium, as also required by claim 21. Indeed, the Examiner admits that "Malaviya ['797] does not specifically disclose the step of positioning a cell growth conduit flap in contact with the synovium." Accordingly, claims 30-33 distinguish over Malaviya '797 at least by virtue of their dependence from claim 21.

**Malaviya '797 in view of Vallee**

The Examiner rejects claims 21, 25, 27, 38, and 40 pursuant to 35 U.S.C. §103(a) as being unpatentable over Malaviya '797 in view of US Patent No. 4,952,404 of Vallee et al. ("Vallee"). Applicants respectfully disagree.

Claim 21 recites positioning the tissue repair scaffold in contact with a defect in a meniscus while positioning the cell growth conduit flap in contact with a tibial surface and the synovium. The Examiner admits that "Malaviya ['797] does not specifically disclose the step of positioning a cell growth conduit flap in contact with the synovium." The Examiner thus relies on Vallee to remedy the deficiencies of Malaviya '797. In this regard, the Examiner asserts that Vallee "teaches that it is known that meniscal tears may be healed if they communicate with the synovial membrane." The Examiner then argues that it would have been obvious to one of ordinary skill in the art at the time of the invention to "modify the placement of Malaviya ['797] such that the covers contact the more vascularized synovium in order to promote healing of the meniscus as taught by Vallee."

At the outset, Vallee merely discloses that "meniscus can be healed by connective tissue provided that the tear communicates with the synovial membrane laterally." Vallee at col. 1, lines 17-19. There is no teaching or suggestion in Vallee regarding the placement of an implant. Moreover, the covers 232, 234 of Malaviya '797, which the Examiner argues form the claimed cell growth conduit flap, cannot be positioned in contact with a tibial surface and the synovium without disregarding the express teachings of Malaviya '797. Malaviya '797 teaches that the "adjacent radially outer portion of the original meniscus" is retained and contacts the device. The retained radially outer portion of the original meniscus thus prevents the device from being positioned in a manner that would allow the covers 232, 234 to contact the synovium. Moreover,

even if the device could be positioned such that the covers 232, 234 contact the synovium, in such a position the device would no longer “conform to the space into which it is inserted such that the surrounding tissue of the remaining meniscus is in contact with the device,” as taught by Malaviya ‘797. *See* Malaviya ‘797 at Par. 0018. Therefore, according to the teachings of Malaviya ‘797, the cell growth conduit flap would not be capable of extending to the synovium. The modification proposed by the Examiner would therefore change the principle of operation of Malaviya. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. MPEP 2143.01(VI); *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). The Examiner therefore fails to present a *prima facie* case of obviousness with respect to claim 21.

Furthermore, claim 21 also recites that the density of the cell growth conduit flap is in the range of about 150 mg/cc to 350 mg/cc. Malaviya ‘797 fails to teach or even suggest a cell growth conduit flap with a density in the range of about 150 mg/cc to 350 mg/cc. The Examiner argues that Malaviya ‘797 discloses that “the covers may have a density in the range of 61-933 mg/cc.” Office Action dated June 9, 2009 at page 5, last paragraph. As discussed above, this is entirely incorrect and is a misrepresentation of the disclosure of Malaviya ‘797. Malaviya ‘797 actually discloses that “a toughened SIS laminate formed from twenty (20) layers of SIS material compressed in a vacuum bed at a temperature of 30° C. for 1 hour was determined to have a density of about 0.933+/-0.061 g/cm<sup>3</sup>.” Malaviya ‘797 at paragraph 0142. Thus, Malaviya ‘797 discloses an SIS laminate that has a density range from 872 mg/cm<sup>3</sup> to 994 mg/cm<sup>3</sup>. The density range disclosed by Malaviya ‘797 is therefore more than 2.5 times higher than the claimed density range. Malaviya ‘797 therefore provides no teaching or suggestion regarding a cell growth conduit flap of the density range required by claim 21.

Accordingly, claim 21, as well as claims 22-23 and 39, which depend therefrom, distinguish over Malaviya ‘797 in view of Vallee and represent allowable subject matter.

Claim 25 recites positioning the cell growth conduit flap in contact with a tissue defect in a meniscus and in contact with a tibial surface and the synovium. Claim 25 also recites that the density of the cell growth conduit flap is in the range of about 150 mg/cc to 350 mg/cc. Applicants arguments with respect to claim 21, above, apply with equal force to claim 25. Accordingly, claim 25, as well as claims 27-29 and 41, which depend therefrom, distinguish over Malaviya ‘797 in view of Vallee and represent allowable subject matter.

**Malaviya '797 in view of Vallee and Li**

The Examiner rejects claims 22, 23, 28, and 29 pursuant to 35 U.S.C. §103(a) as being unpatentable over Malaviya '797 in view of Vallee and further in view of US Patent No. 4,790,819 of Li et al. ("Li"). Applicants respectfully disagree.

Claims 22-23 and claims 28-29 depend from claims 21 and 25, respectively, and therefore distinguish over Malaviya '797 in view of Vallee for all the reasons discussed above with respect to claims 21 and 25. The Examiner admits that Malaviya '797 does not disclose the rasping step recited in claims 22 and 23. The Examiner relies on Li to teach the rasping step. Although Li teaches "using an arthroscopy rasp to abrade the superior and inferior parameniscal synovium," Li does not remedy the deficiencies of Malaviya '797 in view of Vallee with respect to the features recited in claim 21 and 25 from which claims 22-23 and 28-29 depend. *See* Li at Col. 1, lines 27-31.

Li discloses "a delivery device for depositing an exogenous fibrin clot into a wound site during an arthroscopic surgical operation." (Li at Abstract). As discussed above, claims 21 and 25, as amended, recite positioning the cell growth conduit flap in contact with the synovium. In the background of the invention, Li discloses "using an arthroscopy rasp to abrade the superior and inferior parameniscal synovium to increase blood supply to the meniscal tear." (Li at Col. 1, lines 27-31). However, Li does not teach or suggest depositing the fibrin clot material in contact with the synovium. Li merely discloses injecting "a quantity of fibrin clot material into the meniscle tear within the wound site." (Li at Col. 6, lines 63-65). In addition, Li does not disclose using the rasping step in combination with depositing the fibrin clot material. Indeed, Li's invention represents an improvement to methods that require rasping the synovium to create a fibrin clot. Regardless, Li fails to remedy the deficiencies of Malaviya '797 in view of Vallee because Li fails to teach or suggest that the fibrin clot material is placed in contact with the synovium. Claims 22, 23, 28, and 29 therefore distinguish over Malaviya '797 in view of Vallee and Li and represent allowable subject matter.

**Malaviya '797 in view of Schwartz**

The Examiner rejects claims 20 and 34-37 pursuant to 35 U.S.C. §103(a) as being unpatentable over Malaviya '797 in view of US Patent No. 6,468,314 of Schwartz et al. ("Schwartz"). Applicants respectfully disagree.

At the outset, claims 20 and 34-37 ultimately depend from claim 1 and therefore distinguishes over Malaviya '797 for all the reasons discussed above with respect to claim 1. Schwartz fails to remedy the deficiencies of Malaviya '797 with respect to the claimed density of the cell growth conduit flap.

Regardless, with respect to claim 20, the Examiner argues that "it would have been obvious to one of ordinary skill in the art at the time of the invention to modify porous [sic] device of Malaviya to have a void volume *greater than 95%* as taught by Schwartz." (Emphasis added). Such a modification would fail to teach or suggest the claimed invention. Claim 20 recites that the cell growth conduit flap has a void volume *in the range of* about 50% to 95%. However, Schwartz discloses an "insert 16 [...] made substantially of porous material in the form of a matrix or sponge, preferably defining *at least* 95% voids by volume." Schwartz at col. 10, lines 61-63, emphasis added. It is in view of this disclosure that the Examiner suggests that Malaviya be modified to have a void volume "greater than 95%." However, a void volume "greater than 95%" fails to teach or suggest the claimed void volume *in the range of* about 50% to 95%. Thus, even if modified according to the Examiner's suggestion, Malaviya '797 fails to teach or suggest the claimed invention.

Moreover, one of ordinary skill in the art would not have modified the covers 232, 234 of Malaviya '797, which the Examiner argues form the claimed cell growth conduit flap based on the void volume of the insert 16 disclosed by Schwartz. The insert 16 is contained within a porous film 22 formed of bio-absorbable material. Schwartz at col. 9, lines 34-36. Thus, even if it would have been obvious to modify Malaviya '797 in view of Schwartz, presumably one of ordinary skill in the art relying on Schwartz would have modified the mass of biological material 60 contained within the covers, not the covers themselves, to have the at least 95% voids by volume taught by Schwartz. Such a modification would clearly fail to teach or suggest the claimed void volume range of a cell growth conduit flap.

Accordingly, claims 20 and claims 34-37 distinguish over Malaviya '797 in view of Schwartz and represents allowable subject matter.

**Malaviya '797 in view of Vallee and Schwartz**

The Examiner rejects claims 39 and 41 pursuant to 35 U.S.C. §103(a) as being unpatentable over Malaviya '797 in view of Vallee and further in view of Schwartz. Applicants respectfully disagree.

Claims 39 and 41 depend from claims 21 and 25, respectively, and therefore distinguish over Malaviya '797 in view of Vallee for all the reasons discussed above with respect to claims 21 and 25. Moreover, claims 39 and 41 each recite that the cell growth conduit flap has a void volume in the range of about 50% to 95%. Applicants' arguments with respect to claim 20, above, apply with equal force to claims 39 and 41. In brief, Schwartz fails to remedy the deficiencies of Malaviya '797 with respect to the claimed density of the cell growth conduit flap; the modification suggested by the Examiner in view of Schwartz to have a void volume "greater than 95%," would fail to teach or suggest the claimed void volume *in the range of* about 50% to 95%; and Schwartz fails to provide a teaching or suggestion regarding the void volume of a cell growth conduit flap. Accordingly, claims 39 and 41 distinguish over Malaviya '797 in view of Vallee and Schwartz and represent allowable subject matter.

## Conclusion

Applicants submit that all pending claims are allowable, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed necessary to expedite prosecution of this application.

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Respectfully submitted,

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